

which the Secretary determines additional studies are needed to assess the safety and effectiveness of the drug's use in the pediatric population.

In other words, our bill provides for the testing of some cases of these off-patent drugs.

By expanding the mission of the existing NIH Foundation to include collecting and awarding grants for conducting certain pediatric studies, we have provided a funding mechanism for ensuring studies that are completed for both off-patent drugs and those marketed on-patent drugs that a company declines to study—and for which the Secretary determines there is a continuing need for information relating to the use of the drug in the pediatric population.

That is the language in the bill. That is the correct area.

By first seeking funding through the Foundation, we provide a mechanism for drug companies to contribute to the funding of mainly off-patent drugs and also to a narrow group of on-patent drugs, including those for neonates, for which companies have declined to accept the written request to pursue the six month market exclusivity extension.

The Neonates, of course, are young children up to one-month of age.

If the Foundation lacks the funds to study that prioritized drug, the Secretary may then issue a request for proposal—"RFP"—for a third party to study the commercially available drug using money from a Research Fund that we create in this bill. The Secretary may then publish the name of the company that declined to study the drug, the name of the drug, and the indication or use that is being requested to be studied. This would ensure that more data is collected and reported, so that we can better understand which drugs are not being studied.

A condition of the RFP or contract with a third party is that all data and information generated from the pediatric study in the form of a report must be submitted to the NIH and the FDA. The FDA must then review the report and data and negotiate whatever labeling changes the FDA determines is appropriate.

I thank Senator BOND for his determined focus on helping to further ensure that neonates also benefit from this pediatric testing law. I congratulate and thank him. We have included neonates in the definition of "pediatric studies" to which this pediatric exclusivity applies. Throughout the bill we have also encouraged the inclusion of neonates in written requests, when appropriate.

To further ensure that the safety of children in clinical trials is protected, this bill requires that the Institute of Medicine—IOM—conduct a review of federal regulations, reports, and research involving children and provide

recommendations on best practices relating to research involving children. The IOM is to consider the results of the study by HHS that Senator DODD and I included as part of the Children's Health act last year. I look forward to working with Senators DODD, FRIST, and KENNEDY on the issue of human subject protections, especially in focusing on protections of children participating in clinical trials.

I want to thank my friend, Senator DODD for his relentless efforts in making this reauthorization a reality, and for his relentlessness in improving the bill. I look forward to working on many more pediatric initiatives with him in the future.

Let me also thank Senators KENNEDY and CLINTON for their strong support of this bill and of children's health overall. Let me also thank Senator COLLINS for her support and for her work in regard to this bill.

I want to acknowledge and thank Debra Barrett, Jeanne Ireland, Christie Onoda, David Dorsey, David Nexon, Paul Kim, Christina Ho, John Gilman, and Tim Trushel for their hard work in helping us reach agreement on such a well-crafted bill. I cannot think of a bill that took more hard work, more Members and staff than this bill.

I also extend my appreciation to Elaine Holland Vining with the American Academy of Pediatrics for the tenacious effort, technical assistance, and expertise she brought to this bill. She is expecting her first child shortly, and I wish her and her husband, Paul, my very best wishes as they begin their family.

I also appreciate the diligent work of Mark Isaac and Natasha Bilimoria with the Elizabeth Glaser Pediatric AIDS Foundation in helping us negotiate and pass this important reauthorization.

Finally, I must say a very special thanks to a former member of my staff, Helen Rhee, who is now working for Senator FRIST on the HELP Committee. She has been absolutely instrumental in seeing this legislation through from its inception to its passage. Without her tireless efforts, her dogged determination, and a work ethic that is just unsurpassed, we would not be at this point today, we would not have seen this bill pass. Literally, right up until the last moment, literally, before the bill passed, Helen was continuing her work. So I pay tribute to her. This bill is a real tribute to her dedication and to her efforts.

So I thank Helen and all the members of the different staffs who have worked so hard on this bill.

Let me also take a moment to thank Senator HATCH and his staff, Bruce Artim, for their work in drafting language to correct and clarify this bill, specifically to clarify that pediatric exclusivity law is not and was never intended to eliminate incentives granted to generic drug manufacturers that are

awarded 180 days of exclusivity under the 1984 Hatch-Waxman law for successfully challenging a patent.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. DAYTON). The Senator from Vermont.

COMPLETING THE WORK OF THE SENATE

Mr. LEAHY. Mr. President, I see my good friend, the deputy majority leader, the senior Senator from Nevada, in the Chamber. I first note my appreciation for the kind words he has said on several occasions about our efforts in the Judiciary Committee. The Senator and I have been friends from the day he came to the Senate. I value that friendship very much.

I also thank our leadership for having us in session today. Let me take a couple moments to say why.

This is a trying time for everybody—for our staffs, for the brave men and women of the Capitol Police, who protect us, for Dr. Eisol, and all those who work with him in the Capitol physician's office—for everybody, whether they are doorkeepers, or anybody else, including the young pages, both the Democratic and Republican pages who are here. The work is being done. It has been a difficult time.

What would have been more difficult for the Nation would have been if we had not been here today. I think it was essential we be here. We have actually accomplished a great deal by being here.

We have held hearings on judges, and voted a number out of committee, as well as a number of U.S. attorneys. We have completed action on an agreement on the counterterrorism bill. It is something that just a few days ago everybody said could not be done. We have done it. We are now at the point simply of drafting, which is not the easiest thing in the world with all the offices closed down. But the staffs of the various committees, including the Judiciary Committee, of course, have been working literally around the clock to get the paperwork done, to get the actual words on paper.

So I feel safe in predicting the House and the Senate will vote on a package on the counterterrorism bill that, interestingly enough, will be improved over what we passed in the Senate and improved over what they passed in the other body.

The sum is greater than the parts. And that shows what happens when we work together—both bodies; both parties—to get something done.

We have actually done the administration a favor by taking time to look at it. The piece of legislation originally proposed by the White House and Attorney General was deeply flawed. Had we accepted their proposal to immediately move forward and pass it, we would have given them a flawed bill

which, in the long run, would have hurt their chances to fight terrorism.

The distinguished Presiding Officer, the Senator from Minnesota, was one of those who cautioned and counseled both me and others to go slowly, look at what is here, and make sure we do it right.

The distinguished Senator from Minnesota, as he always does, offered wise counsel. The distinguished Senator from Nevada, Mr. REID, stood in this Chamber a number of times and said: We want to get it done right. I believe we have.

But lastly, it is important, as a symbol, that we be in session. I feel deeply privileged to be a Member of the Senate. I remember the first day I walked in this Senate Chamber as a Senator-elect. I was a 34-year-old prosecutor from Vermont. I had never been on the floor of the Senate. It was a lameduck session after the elections at the time. We were going to go into the new session, which is when I would be sworn in.

I came in as a Senator-elect. I thought to myself: What a thrill, coming in this Chamber and seeing people, giants of the Senate—in fact, two predecessors from the Presiding Officer's home State: Hubert Humphrey and Fritz Mondale. And I have thought it a privilege every day I have walked in this Chamber, every day I have come to this building.

I have no idea how long I will be a Senator—none of us do—but I know every single day that I am, I will consider it a day that is a great privilege.

And this building, this symbol of democracy, which will be here long after all 100 of us are gone—and I hope for hundreds and hundreds more it will be here—should be open. It should be open. It should tell not just a quarter of a billion Americans that this is the seat of democracy but tell billions of people around the world, especially those who come from countries that are anything but democracies, this symbol stands, this symbol shines, this symbol is open for business.

Mr. President, I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. REID. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

JUDICIAL NOMINATIONS

Mr. REID. Mr. President, I want to go over a few facts regarding judicial nominations because that has been the subject of some discussion in this Chamber.

I, first, say that today there was a hearing held down in S-128, the appro-

priations room. It was held in spite of all that is going on around here. I want to tell Senator LEAHY how much I appreciate that, and also Senator SCHUMER, who chaired the subcommittee.

I say that because Senator ENSIGN nominated Larry Hicks. He did it. And I appreciate very much JOHN ENSIGN allowing me to approve of his nomination.

JOHN has been very good about that. Every fourth nomination I get. He told me if there is somebody I really don't like, he said, yes, he wouldn't put them forward. But the first person he put forward is a man by the name of Larry Hicks, eminently qualified, a good lawyer and a good person. It would have been a terrible shame for him and his family to have traveled back here yesterday to be told the hearing has been canceled, the Senate is not in session. So they were able to go into that crowded room and proudly be there when their husband, their father, their brother was given this most important hearing that will make him a Federal judge. He is extremely well qualified.

I wish to tell the Senator from Vermont how much I personally appreciate that. He is chairman of the committee. He is the one who arranged that. He is a member of the Appropriations Committee, one of the senior members. That is why we were able to use S-128.

Not only did he hold the hearing in S-128, but there was an emergency meeting held today to mark up people who had had hearings previously. Thirteen U.S. attorneys were reported out of the Judiciary Committee today, including a person who is going to be an assistant Attorney General, Jay Bybee from Nevada, a person also very well qualified, a professor at the University of Nevada Law School.

In addition to the U.S. attorneys and the Assistant Attorney General, we have four district court judges who were reported out of committee. Right back here it was done. It was difficult to get a quorum. People were pulled off the floor to do that. The Senator from Vermont, chairman of the committee, did that. There was a judge from Oklahoma, a judge from Kentucky, a judge from Nebraska, and a judge from Oklahoma—four district court judges.

In S-128 today, there was not a single member of the minority at that committee hearing—not a single one. The makeup of the committee was Senator SCHUMER, Senator LEAHY, and Senator KENNEDY. I may be missing someone but they were all Democrats. So I say to my friends, if these judicial nominations are that important, couldn't they attend a hearing? Remember, these were all Republican nominations—not a single Democratic nomination, all Republicans.

Let me also say this to boast—it is a pure, unadulterated boast; I am bragging about Chairman PAT LEAHY—con-

firmations under Chairman LEAHY have been faster than in the other first years. Fair comparisons show that by October 15 of the first year of President Clinton's administration, the Senate had only confirmed four judges, four fewer than by the same time this year. By October 15 of the first year of the first Bush administration, the number was the same; only four judges had been confirmed. This year, 2001, in the fewer than 4 months since the reorganization of the Senate, when we had Chairman LEAHY of the Judiciary Committee, and we had to spend some time organizing, too—you don't just hit the ground running—twice as many judges have been confirmed as during the first 9 months of the first Bush administration and the Clinton administration. Remember, 4 months.

Chairman LEAHY and the Senate are ahead of the confirmation pace for judicial nominations for the first year of the Bush administration and the first year of the Clinton administration.

Since July of this year, the Senate has already confirmed four court of appeals judges and a fifth has already had a hearing and is being scheduled for committee consideration as soon as the followup questions are answered. That judge would have been reported out today had the questions been answered of one of the Senators, I believe from Wisconsin. Senator FEINGOLD had some questions that had not been answered. Because of that and Senate tradition, you can't report out nominations if questions of members of the committee have not been answered.

In 1989, five court of appeals judges were confirmed for the entire year. We are on a pace to confirm between six and eight this year.

Chairman LEAHY has already held six hearings involving judicial nominees since July 10, including two in July and two unprecedented hearings during the August recess. Most of us were out doing other things. I am not afraid to acknowledge, I took a vacation for several weeks in August. When PAT LEAHY was here holding hearings, I was vacationing. Unprecedented hearings, two hearings during August, a hearing in September in the aftermath of the September 11 terrorist attack, a hearing on October 4, and, of course, the hearing today about which I have talked.

By contrast, in the 6½ years the Republicans chaired the Judiciary Committee from 1995 to 2001, in 34 months, they held no confirmation hearings for judicial nominations, 34 months. In 30 months, they held a single confirmation hearing. And in only 12 months did they hold at least two hearings involving judicial nominees.

You can bring charts on the floor, as was done earlier saying, Senator LEAHY, when he holds a hearing, doesn't do as many as we did. As I have said, I am happy to play this statistics game. I am happy to do that. Anyone